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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,894	01/09/2002	Jinrui Shi	1286	5731

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EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

M

Office Action Summary

Application No.

10/042,894

Applicant(s)

SHI ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-11 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-4,6-11 and 14-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/4/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE Acknowledgment

1. The request filed on 6/7/2005 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 10/042,894 is acceptable and a RCE has been established. An action on the RCE follows.

2. Claims 1, 3-4, 6-11, 14-21 including SEQ ID NO:7 encoding SEQ ID NO:8 are pending and are examined in the present office action.

Claims 2, 5, 12-13, and 22-68 have been canceled.

Enablement

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3-4, 6-11, and 14-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by

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one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated nucleic acid comprising a polynucleotide encoding the polypeptide of SEQ ID NO:8 wherein the polypeptide has inositol polyphosphate kinase (IPPK) activity, or a polynucleotide having the sequence set forth in SEQ ID NO:7, or a polynucleotide which is complementary to said polynucleotide, vector, expression cassette, non-human host cell, and plant transformed therewith, and method for modulating inositol polyphosphate kinase activity in a host cell or plant and method of decreasing the level of phosphorous in non-ruminant animal waste, comprising transforming said host cell or plant with said polynucleotide.

The Office interprets "a polynucleotide which is complementary to a polynucleotide" to read on a large number of sequences because the recitation reads on as little two base pairs.

Applicants isolated a cDNA clone from a maize cDNA library using primers comprising SEQ ID NO:26 and 27. The isolated cDNA of SEQ ID NO:7 encodes an IPPK protein of SEQ ID NO:8 (pages 36-39, Examples 1-3; and sequence listing). Applicants disclose the introduction of said cDNA sequence into immature maize embryos (pages 43-44, section B)

Because Applicants elected Group I drawn to nucleic acids in sense orientation and did not elect Group III drawn to antisense, the Office interprets this election to mean that Applicants' invention is drawn to over-expressing SEQ ID NO:7 in a plant to increase the activity of IPPK.

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Applicants have not reduced to practice the claimed invention. Applicants only disclosed the cloning of SEQ ID NO:7 encoding SEQ ID NO:8, but Applicants do not disclose the outcome of transforming said sequence into maize or any plant. Applicants do not report if the introduced nucleic acid increased the phytic acid content or if inositol polyphosphate kinase activity or levels were increased. Applicants do not teach by way of example the use of the claimed sequences to modulate IPPK activity or levels.

Applicants are claiming a series of plants overexpressing a nucleic acid sequence encoding inositol polyphosphate kinase operably linked in sense orientation with the intention of modulating the activity of said endogenous gene with an ultimate goal of reducing the phytate levels of seeds. But, based on Applicants' disclosure, overexpressing SEQ ID NO:7 will increase the activity of IPPK of SEQ ID NO:8, thereby increasing the phytate level, decreasing the level of non-phytate phosphorous of a plant and increasing the level of phosphorous in non-ruminant animal waste. In addition, the state-of-the-art teaches that "the biosynthetic route leading to phytate is complex and not completely understood" (Martino-Catt et al, March 6, 2001, U.S. Patent Number 6,197,561; column 2, lines 59-61). Bohnert et al (1995, The Plant Cell 7:1099-1111) teach that myo-inositol 1-phosphate is a substrate/starting material for many diverse products other than phytate (page 1102, Figure 1).

Applicants' claims are broadly drawn to any nucleic acid based on the recitation of "a polynucleotide which is complementary" as discussed above. It is clear to one of skill in the art that transforming a plant with "any" polynucleotide will not modulate the IPPK activity in any plant.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:7 as probes or by designing primers to undisclosed regions of SEQ ID NO:8 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed have inositol polyphosphate activity and exhibit 75% sequence identity with SEQ ID NO:7.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-4, and 6-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Ooijen et al (January 1997, U.S. Patent 5,593,963).

The claims are drawn to a polynucleotide which is complementary to a polynucleotide encoding the polypeptide of SEQ ID NO:8 or a polynucleotide having the sequence set forth in SEQ ID NO:7; a vector comprising said polynucleotide, an expression cassette comprising said polynucleotide operably linked to a promoter, a non-human host cell or plant comprising said polynucleotide, or wherein the plant is canola or a transgenic seed comprising said polynucleotide.

The Office interprets “a polynucleotide which is complementary to a polynucleotide” to read on a large number of sequences because the recitation reads on as little two base pairs.

Van Ooijen et al disclose an isolated nucleic acid sequence which comprises a complement sequence of Applicants’ claimed sequences, as discussed above. Van Ooijen et al disclose an expression vector comprising said isolated nucleic acid, operably linked to the Cauliflower Mosaic Virus (CaMV) 35S promoter, wherein the nucleic acid encodes a phytase (columns 12-13, Example 4). Van Ooijen et al disclose transforming tobacco with a vector comprising said nucleic acid operably linked to the CaMV 35S promoter using *Agrobacterium* (column 14, Example 6). Van Ooijen et al also disclose transformed tobacco seeds comprising transforming tobacco seeds with a vector comprising said nucleic acid operably linked to a seed specific promoter and transformed rapeseed (canola) plants comprising said vector (columns 15-16, Examples 8 and 9). It would be inherent that the transformed rapeseed would produce transgenic seeds, and as such, Van Ooijen et al anticipate the claimed invention.

5. No claims are allowed.

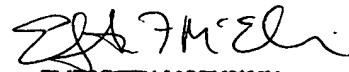
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
July 13, 2005


ELIZABETH MCELWAIN
PRIMARY EXAMINER